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Attorney General Bruning Announces Settlement with Pharmaceutical Manufacturers

Nebraska Receives \$100,000

Note: A sound bite on this topic will be available shortly at: www.ago.ne.gov

(Lincoln, Neb.) Attorney General Jon Bruning today announced that Merck & Co. Inc., Schering-Plough Corporation, and a joint venture of the two companies, MSP Singapore Company, LLC paid \$100,000 to the State of Nebraska. The multistate settlement resolves an investigation into the companies' lengthy delay releasing negative results from a clinical trial involving the cholesterol-lowing drug Vytorin.

In the study, Vytorin (a combination of the drug Zetia and simvastatin) was no more effective reducing formation of plaque in carotid arteries than the less expensive, generically available cholesterol-lowering drug simvastatin. Although the trial ended in May 2006, a partial reporting of negative results didn't occur until January 2008, and complete results were not published until the following April. Prior to release of the results, Vytorin had been heavily promoted in direct-to-consumer advertisements.

"It's important for pharmaceutical companies to be forthcoming with data surrounding the effectiveness of their drugs," said Bruning. "Transparency is essential. Consumers need the most current information to make educated decisions about their health."

Under the settlement, the companies must follow the following requirements for Vytorin and Zetia:

- Obtain pre-approval from FDA for all direct-to-consumer television advertisements;
- Comply with FDA suggestions to modify drug advertising;
- Register clinical trials and post their results;
- Prohibit ghost writing of articles;
- Comply with detailed rules prohibiting the deceptive use of clinical trials.

The companies agreed to pay a total of \$5.4 million to 36 states.

Assistant Attorney General Leslie Levy handled the case.